REMARKS

Claims 1-6 and 8-14 are pending. Claims 8-13 have been withdrawn. Claim 1 is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Claims 1-6 and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 ("Sunshine et al."), U.S. Patent No. 4,943,565 ("Tencza et al."), Remington's Pharmaceutical Sciences p. 1837 ("Remington"), and U.S. Patent No. 6,602,520 ("Schroeder et al."). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Claim 1 of the present invention is directed to a solid pharmaceutical dosage form that includes the noteworthy features of a caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having an average particle size of about 70 to 600 microns, and wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Applicants have previously discussed Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al. For at least the reasons stated previously, it is respectfully submitted that none of the references cited, i.e., Sunshine et al., Tencza et al., Remington, and Schroeder et al., teach or suggest the inclusion of caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having an average particle size of about 70 to 600 microns, and wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, in a solid pharmaceutical dosage form.

Applicants respectfully submit that the proposed combination of Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al. would result in a solid pharmaceutical dosage form that includes caffeine, wherein at least 75% of the dosage form, dissolves in less than 45 minutes. In contrast, the pharmaceutical dosage form recited in Claim 1 includes uncoated ungranulated caffeine, wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Clearly caffeine dissolution at a rate of at least 86% dissolution within 5 minutes is far superior to a dissolution rate of at least 75% of the dosage form in less than 45 minutes. Applicants note that the improved rate of dissolution is due to the use of uncoated ungranulated caffeine. As such, Claim 1 is patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., whether considered separately or in combination.

On page 10 of the present Office Action, the Examiner states that "[a]mended claim 1 is considered obvious because it would be obvious that at least 95% of the caffeine in the caffeine composition tablet of Tencza et al. would be dissolved within 5 minutes since the reference teaches that at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes."

Applicants respectfully disagree. It is respectfully submitted that Tencza et al. only teaches that at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes. As noted above, a dissolution rate of at least 86% dissolution within 5 minutes is far superior to a dissolution rate of at least 75% of the dosage form in less than 45 minutes. At least 86% is a significantly greater amount than at least 75%. This is especially true given the time constraint of within 5 minutes as recited in Claim 1, versus the less than 45 minutes disclosed by Tencza et al. The uncoated ungranulated caffeine used by Applicants helps achieve the

surprisingly superior dissolution rate of the claimed dosage form over the granulated caffeine used in Tencza et al.

If the Examiner believes otherwise, then Applicants respectfully request that the Examiner clarify her position and explain why she believes that a dissolution rate of at least 86% dissolution within 5 minutes is not superior to or better than a dissolution rate of at least 75% of the dosage form in less than 45 minutes.

The Examiner further states that the "prior art teaches the preparation of rapid disintegrating tablets by using the same ingredients and teaches all the factors which influence the disintegration so at the time of the invention was filed it would have been obvious to prepare such tablets." See Office Action dated January 19, 2010, p. 9, lines 5-7.

Applicants respectfully disagree. Applicants emphasize that the caffeine used by Tencza et al. is not the same as the uncoated ungranulated caffeine utilized in the presently claimed solid dosage form. The uncoated ungranulated caffeine utilized by Applicants helps achieve the higher and faster dissolution rate recited in Claim 1.

As such, Claim 1 is patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., whether considered separately or in combination.

Claims 2-6 and 14 directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 and 14 are patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., taken separately or in combination.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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